

EXHIBIT U



OPTN/UNOS Ad Hoc Committee on Geography

Geographic Organ Distribution Principles and Models Recommendations Report

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Geographic Organ Distribution Principles and Models Recommendations Report

Mini-Brief

Executive Background

The Ad Hoc Committee on Geography (the Committee) was formed in December 2017 to examine the principles of geographic distribution of organs. The Committee was charged with:

- Establishing defined guiding principles for the use of geographic constraints in organ allocation
- Reviewing and recommending models for incorporating geographic principles into allocation policies
- Identifying uniform concepts for organ specific allocation policies in light of the requirements of the OPTN Final Rule

The OPTN Final Rule sets requirements for allocation policies developed by the OPTN, including sound medical judgement, best use of organs, the ability for centers to decide whether to accept an organ offer, to avoid wasting organs, and to promote efficiency. The Final Rule also includes a requirement that policies "shall not be based on the candidate's place of residence or place of listing, except to the extent required" by the other requirements of the Rule.

The geographic requirement in the Final Rule is stated differently from the other requirements. The OPTN is allowed to create allocation policies that include some preference for candidates that are proximate to a donor, but only when those preferences are based on the other factors established in the Final Rule.

Recent external questions about geography demonstrated the need for the OPTN to be more specific in clearly stating the geographic principles that the OPTN has used to make to create the policies that exist today. The Committee was created to help develop a more formal process for framing, guiding, and communicating the decisions that organ specific committees are making about geography.

The Committee includes various leaders in the transplant community representing diverse perspectives. Half of the Committee are OPTN/UNOS Committee chairs or vice-chairs, representing each organ and other professional perspectives. The other half were Board of Directors members that represented stakeholders in the community, including vulnerable populations, professional societies, patients, and members with experience in geographic organ distribution projects. (See *Committee Roster*, page 8)

The Committee met six times between January 2018 and April 2018. This report highlights important decisions and consensus of the Committee and recommends next steps for the Board of Directors to consider.

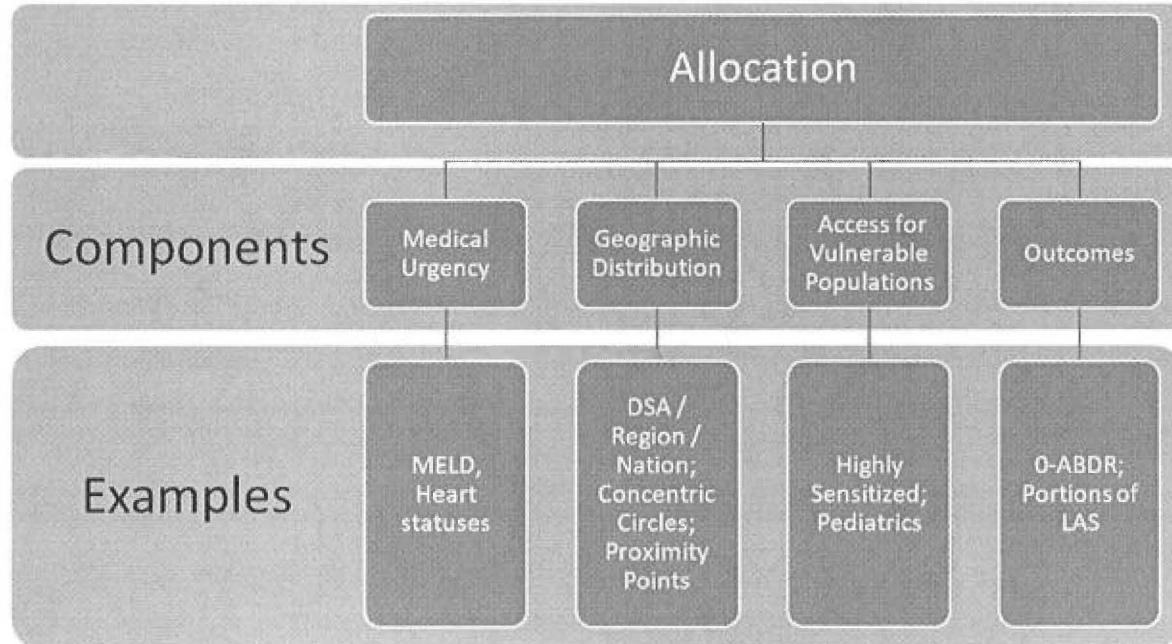
Geographic Organ Distribution Principles and Models Recommendations Report

Sponsoring Committee: Ad Hoc Geography Committee

Geographic Organ Distribution Focus

Geography is one of several components in allocation policies. Allocation includes factors for medical urgency, geographic location, access for vulnerable populations, and outcomes. The Committee's charge was to focus only on the principles and frameworks used by the OPTN to determine geographic components. The Committee noted that decision tools for policy committees that make it easier to discuss components individually would be helpful for policy development discussions.

Figure 1: The role of geographic distribution among other factors in organ allocation



The Committee focused on establishing defined principles and models of organ distribution that align with the Final Rule and are applicable to all organ allocation systems. The Geography Committee did not attempt to recommend changes to organ-specific allocation policies. Organ-specific committee leaders on the Geography Committee agree that the work of the Geography Committee can inform subsequent reviews and analysis by the organ-specific committees of each organ allocation system.

Geographic Organ Distribution Principles

The Geography Committee recommends to the Board of Directors that allocation policies demonstrably incorporate the geographic principles described below.

Deceased donor organs are a national resource to be distributed as broadly as feasible. Any geographic constraints pertaining to the principles of organ distribution must be rationally determined and consistently applied.

Geographic distribution may be constrained in order to:

1. Reduce inherent differences in the ratio of donor supply and demand across the country
2. Reduce travel time expected to have a clinically significant effect on ischemic time and organ quality
3. Increase organ utilization and prevent organ wastage
4. Increase efficiencies of donation and transplant system resources

These principles are in agreement with the OPTN's legal obligations under the final rule.

| Principle of Distribution | Final Rule Requirement |
|--|--|
| Deceased donor organs are a national resource to be distributed as broadly as feasible | <i>Final Rule §121.8(a) states, "... allocation policies: (8) Shall not be based on the candidate's place of residence of listing ..." Final Rule §121.8(b) states, "Allocation policies shall be designed to achieve equitable allocation of organs among patients... through the following performance goals, (3) distributing organs over as broad a geographic area as feasible ..."</i> |
| Reduce inherent differences in the ratio of donor supply and demand across the country | <i>Final Rule §121.8(a) states, "... allocation policies: (5) Shall be designed to ... promote patient access to transplantation, and to promote the efficient management of organ placement."</i> |
| Reduce travel time expected to have a clinically significant effect on ischemic time and organ quality | <i>Final Rule §121.8(a) states, "... allocation policies: (1) Shall be based on sound medical judgment; (5) Shall be designed to avoid wasting organs..."</i> |
| Increase organ utilization and prevent organ wastage | <i>Final Rule: §121.8(a) states, "... allocation policies: (5) Shall be designed to avoid wasting organs ..."</i> |
| Increase efficiencies of donation and transplant system resources | <i>Final Rule: §121.8(a) states, "... allocation policies: (5) Shall be designed to ... promote the efficient management of organ placement..."</i> |

Deceased donor organs are a national resource to be distributed as broadly as feasible. Any geographic constraints pertaining to the principles of organ distribution must be rationally determined and consistently applied to minimize the effect of geography on a candidate's access to transplantation

Final Rule §121.8(a) states, "... allocation policies: (8) Shall not be based on the candidate's place of residence of listing ..." Final Rule §121.8(b) states, "Allocation policies shall be designed to achieve equitable allocation of organs among patients... through the following performance goals, (3) distributing organs over as broad a geographic area as feasible ..."

This over-arching principle ensures alignment with the Final Rule and allows for a defensible system of distribution.

For example, geographic boundaries for organ distribution that are not based on evidence or objective support would be arbitrary and cannot be defensible as an organ distribution constraint. The OPTN must have a rational basis for allocation and distribution. Any geographic constraints for organ distribution must be consistent, intentional, measurable, and in alignment with the mandates of the Final Rule.

OPTN/UNOS Mini-Brief

The Committee agrees that considering donated organs as a national resource is the approach that is most consistent with the Final Rule, with our national donation and transplant community, and with donor family wishes.

The Final Rule requires that geographic distribution be limited only for specified reasons. The OPTN board and committee system are set up to provide governance to a national community. Additionally, multiple public opinion surveys throughout the years show that donor families want donated organs to go to candidates in need, regardless of where they live. The Committee rejects the notion that organs are inherently locally owned.

Geographic distribution may be constrained in order to reduce inherent differences in the ratio of donor supply and demand across the country

Final Rule §121.8(a) states, "... allocation policies: (5) Shall be designed to ... promote patient access to transplantation, and to promote the efficient management of organ placement."

Differences in local demographics such as death rates and disease prevalence create differences in access to transplant between individual candidates. Even as the OPTN works with the community to promote improvement in OPO and transplant hospital practices that add to inherent demographic variations, the larger population factors will continue to make it more difficult for candidates in some areas of the country to receive organ offers than for others. Organ allocation policies should aim to make access for comparably medically urgent candidates similar no matter where they are listed for transplant, subject only to the other principles on this list.

Geographic distribution may be constrained in order to reduce travel time expected to have a clinically significant effect on ischemic time and organ quality

Final Rule §121.8(a) states, "... allocation policies: (1) Shall be based on sound medical judgment; (5) Shall be designed to avoid wasting organs..."

The Final Rule does not ask the OPTN to make harmful medical decisions in pursuit of geographic equality. When the distance a donor organ must travel can cause inferior graft outcomes for the recipient, it is an appropriate restriction on geographic distribution.

Not all ischemic time is a result of travel time, but to the extent that additional travel increases the damage done by cold time, allocation policies may take that damage into account. This principle does not attempt to define cold time factors for allocation policies. Those factors are different for each organ, and even among donor types (DBD/DCD) within each organ. What's more, they may change over time as new technologies reduce the detrimental effects of additional travel.

Geographic distribution may be constrained in order to increase organ utilization and prevent organ wastage

Final Rule: §121.8(a) states, "... allocation policies: (5) Shall be designed to avoid wasting organs ..."

As with the principle above, the Final Rule does not insist that the OPTN create wasteful rules. Geographic distribution may be constrained when broader distribution would lead to more organ discards. Serving our national patient population best includes increasing the number of transplants and reducing the number of recovered organs that ultimately go untransplanted.

Geographic distribution may be constrained in order to increase efficiencies of donation and transplant system resources

Final Rule: §121.8(a) states, "... allocation policies: (5) Shall be designed to ... promote the efficient management of organ placement..."

There are practical and financial considerations in operating an organ allocation system. Air transportation costs significantly more than ground transportation. To the extent that transplant teams travel to recover organs themselves, they have less time available in their own hospitals to perform transplants. There are other logistical and practical challenges to offering each organ to a greater number of centers. To the extent that these challenges cannot be addressed through other means, and that they are objectively defined and identified by the policy making committees, these considerations can lead to appropriate restrictions on geographic distribution.

Themes of Geographic Organ Distribution Models

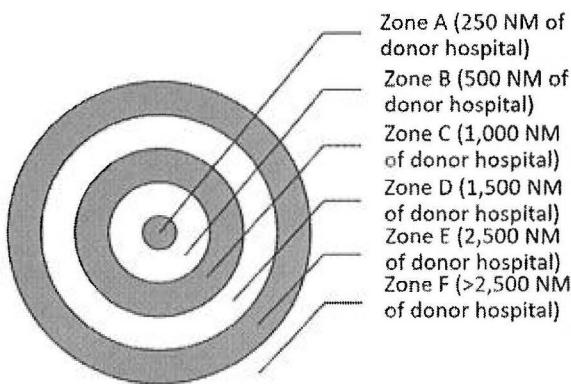
The Committee also identified three frameworks for geographic distribution that it finds to be consistent with the principles above and with the Final Rule. The Committee recommends further discussion by the Board and by the community of the merits of the three frameworks, but agrees that the system would be best served by adopting a single common framework to be applied to all organ allocation policies. Even within a common framework, each organ would have medically determined factors that apply specifically to that organ. The three frameworks identified by the Committee are:

1. Organ Distribution Based on Fixed Distance from the Donor Hospital
2. Organ Distribution Based on Mathematical Optimization
3. Organ Distribution without Geographic Boundaries

Organ Distribution Based on Fixed Distance from the Donor Hospital

One of the recommended frameworks utilizes a system of fixed geographic units based on the distance from the donor hospital to the candidate's place of listing. One example of this framework is currently utilized in heart and lung distribution and referred to as concentric circles. The changes to liver distribution approved by the Board of Directors in December 2017 partially utilizes a similar concept to add a proximity circle around a donor hospital, however the changes to liver distribution still maintain the regional boundaries and the proximity circle expands the geographic unit of allocation outside of the region.

Figure 2: Current Lung Distribution Policy, concentric circles around the donor hospital



The Committee discussed several advantages of this distribution model and its alignment with the principles. Distance from a donor hospital is related to ischemic time of an organ, therefore organ-specific constraints could be chosen based on considerations for travel time and donor characteristics. The size constraints of the circle can also reduce inherent differences in potential donor supply and demand by broadening distribution across multiple DSAs and current regional boundaries. Additionally, the use of concentric circles can minimize travel of organs for patients with similar allocation priority by ordering candidates within a zone by organ-specific measures of medical urgency. For example, lung distribution candidates are ordered within a "zone" by their lung allocation score (LAS). Similar stratification can be achieved in other organs by their medical urgency score (MELD score for liver distribution) or by waiting time.

A disadvantage of this distribution model is the inherent "cliffs" between each concentric circle. For example, within a policy that employs 500 mile circles, a candidate at a transplant program 499 miles away from the donor hospital and another candidate 501 miles away from the donor hospital are treated differently, although in terms of geographic proximity they are very similar. Those differences are smaller in circle models that assign some number of proximity points to each circle than in circle models that offer to all candidates within one circle before offering to the subsequent circle.

Any proposal to incorporate circles into allocation policies should clearly define the relationship between the selection of the circle sizes and the principles of geography.

Organ Distribution Based on Mathematical Optimized Boundaries

The use of mathematical optimization in organ distribution has been discussed previously with the development of the changes to liver distribution. In this model, one or more objectives (minimize effect of geography, pre-transplant deaths, etc.) and possible constraints (amount of travel, supply and demand, etc.) are used to create the optimal distribution system. The Committee was presented with several models that utilize this approach including *Optimized Districts*, *Optimized Neighborhoods*, and *Population Density Bubbles*. The specifics of each model vary, however the goal of each is the same, to create an optimal geographic distribution area based on pre-determined metrics and constraints.

Figure 3: Example of Population Density Bubbles depicting the difference between a fixed radius circle (400 miles) and a fixed population circle (at least 50,000,000 population) around a transplant center

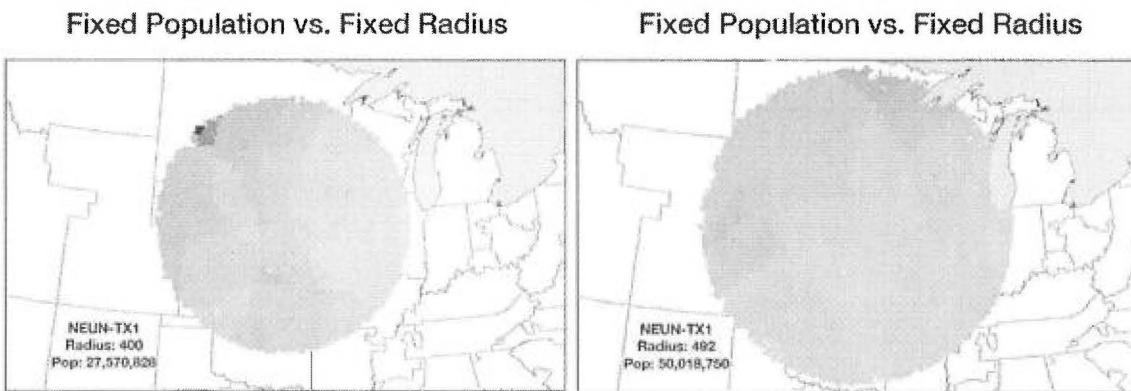
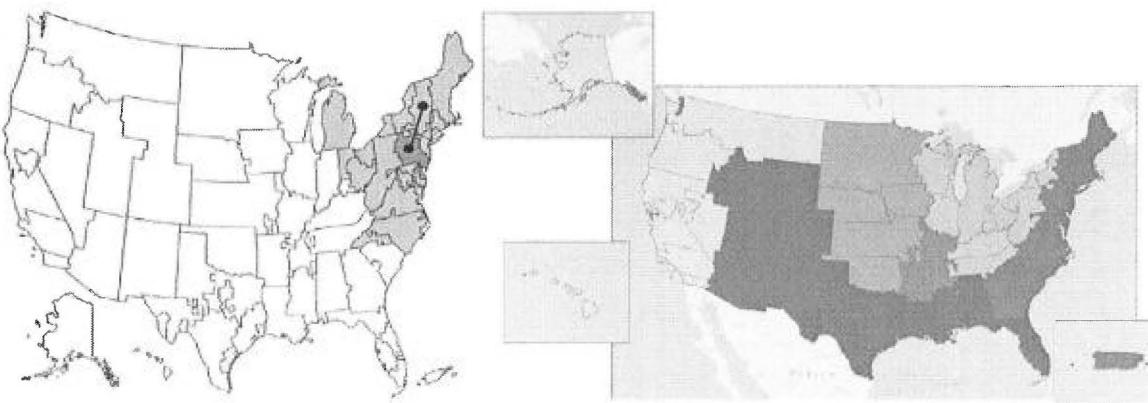


Figure 4: Example of Optimized Neighborhoods¹ and Optimized Districts



The use of metrics and constraints to select the geographic distribution area reduces the concern for arbitrarily defined geographic borders of distribution. There is flexibility to allow organ-specific variation details due to variation in ischemic time and donor characteristics. As long as the input constraints are consistent with the geographic principles and the Final Rule, mathematically optimized units of distribution are ethically and legally defensible. Concern for system resources and efficient operation of the OPTN

¹ Sanjay Mehrotra, PhD, Vikram Kilambi, PhD, Kevin Bui, MS, Richard Gilroy, MD, Sophoclis P. Alexopoulos, MD, David S. Goldberg, MD, MSCE, Daniela P. Ladner, MD, MPH, and Goran B. Klintmalm, MD, PhD; A Concentric Neighborhood Solution to Disparity in Liver Access That Contains Current UNOS Districts; Transplantation, February 2018, Volume 102, Number 2

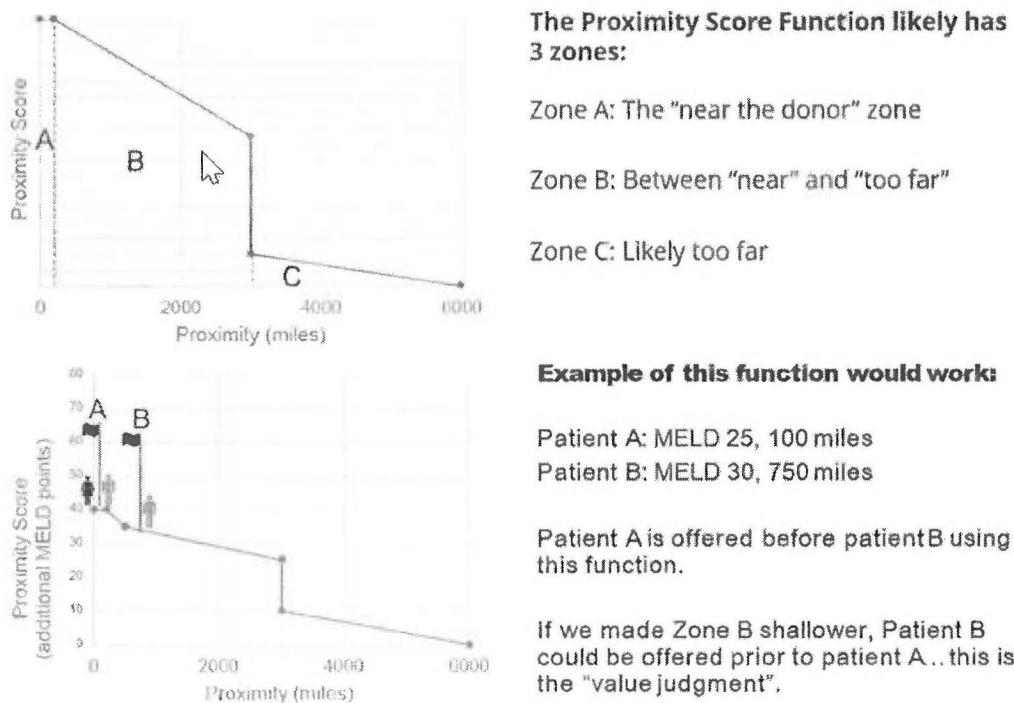
can be addressed by constraining the extent of organ travel and number of programs within any given geographical unit.

Hypothetically, most concerns with this approach could be addressed in the optimization. However, optimized units have been not been well-received by the community in the past. Many versions of this model still retain fixed borders that create the possibility of two similarly situated candidates on either side of the border receiving different levels of access to organs. Additionally, optimized distribution models that utilize existing donor service areas as a building block are fundamentally flawed given the variation in DSA characteristics (size, population density, etc.) throughout the country.

Organ Distribution without Geographic Boundaries

The model of organ distribution without geographic boundaries incorporates proximity of candidates to a donor through an algorithm designed to account for the principles above (e.g.; outcomes, discards, efficiency), rather than by being inside or outside a boundary. The concept reviewed by the Committee proposed that candidates' *Allocation Priority Score* would be made up of a *Medical Priority Score* plus a *Proximity Score*. By using this kind of calculation, there would not be absolute geographic boundaries and candidates would be ranked on a match run based on a combination of their clinical characteristics and proximity to a donor.

Figure 5: Depiction of the proximity score under the concept of distribution without boundaries



The Committee discussed several advantages of this distribution model and its alignment with the principles. Concern over fixed geographic boundaries separating candidates and donors is eliminated. This distribution model is theoretically similar to the idea of concentric circles and zones, except the fixed "cliff" that separates candidates in their respective zones would be a much more smooth transition, rather than an absolute boundary based on distance.

This model could be uniform across the organs and the specifics (medical priority and proximity score) could be specific to the clinical characteristics and ischemic considerations of each organ. This would require significant discussion by the organ-specific stakeholders to identify the medical and geographic thresholds to prioritize candidates.

Recommendations and Next Steps

I. Board of Directors approve the proposed Principles of Organ Distribution:

Deceased donor organs are a national resource to be distributed as broadly as feasible. Any geographic constraints pertaining to the principles of organ distribution must be rationally determined and consistently applied.

Geographic distribution may be constrained in order to:

1. Reduce inherent differences in the ratio of donor supply and demand across the country
2. Reduce travel time expected to have a clinically significant effect on ischemic time and organ quality
3. Increase organ utilization and prevent organ wastage
4. Increase efficiencies of donation and transplant system resources

- II. Request community feedback on the recommended distribution frameworks with a goal of identifying a single, preferred distribution framework to be used across organ types.
- III. Perform a policy analysis of current organ distribution policies in reference to the proposed principles of organ distribution.
- IV. Maintain the Ad Hoc Geography Committee through the remainder of 2018 to receive and respond to community feedback and to facilitate conversations among organ-specific committee leadership about policy analysis.

Committee Roster

| Role | Name | City/State | Region |
|---|----------------------|-----------------|--------|
| AOPO Representative and Chair of Committee | Kevin O'Connor | Seattle, WA | 6 |
| BOD - Regional Councilor Representative | Adam W. Bingaman | San Antonio, TX | 4 |
| BOD - Regional Councilor Representative | Lew Teperman | New York, NY | 9 |
| BOD - At-Large (M.D.) Representative | W. Kenneth Washburn | Columbus, OH | 10 |
| BOD - Minority Transplant Professional Representative | Akinlolu Ojo | Tucson, AZ | 5 |
| BOD - AOPO Representative | Charles Alexander | Baltimore, MD | 2 |
| BOD - At-Large OPO Representative | Alexandra K. Glazier | Waltham, MA | 1 |
| BOD - General Public Representative | Deanna L. Santana | Placerville, CA | 5 |
| BOD - Vice President, Patient & Donor Affairs | Kenyon W. Murphy | Franklin, NC | 11 |
| AST Representative | Richard Formica | New Haven, CT | 1 |
| ASTS Representative | Charles Miller | Cleveland, OH | 10 |
| Chair, Kidney | Nicole Turgeon | Atlanta, GA | 3 |
| Chair, Liver | Julie Heimbach | Rochester, MN | 7 |

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| Role | Name | City/State | Region |
|----------------------|------------------|---------------|--------|
| Chair, Thoracic | Kevin Chan | Ann Arbor, MI | 10 |
| Vice Chair, Thoracic | Ryan Davies | Dallas, TX | 4 |
| Vice Chair, Pancreas | Silke Niederhaus | Baltimore, MD | 2 |
| Chair, OPO | Jennifer Prinz | Denver, CO | 8 |
| Chair, TAC | James Pittman | Nashville, TN | 11 |
| Chair, Ethics | Elisa Gordon | Chicago, IL | 7 |

OPTN/UNOS Mini-Brief

Recommended Principles

1 RESOLVED, that the Principles of Geographic Distribution, as set forth below, are hereby
2 approved, effective June 12, 2018.

3
4 The recommendations from the Committee below are proposed new language put forth for consideration;
5 underlines have been omitted for easier reading.

Principles of Organ Distribution

8 Deceased donor organs are a national resource to be distributed as broadly as feasible. Any geographic
9 constraints pertaining to the principles of organ distribution must be rationally determined and consistently
10 applied.

11 Geographic distribution may be constrained in order to:

14 1. Reduce inherent differences in the ratio of donor supply and demand across the country
15 2. Reduce travel time expected to have a clinically significant effect on ischemic time and organ quality
16 3. Increase organ utilization and prevent organ wastage
17 4. Increase efficiencies of donation and transplant system resources

18 **FURTHER RESOLVED, that further recommendations from the Ad Hoc Geography Committee, as
19 set forth below, are hereby accepted, effective June 12, 2018.**

22 1. Request community feedback on the recommended distribution frameworks with a goal of identifying
23 a single, preferred distribution framework to be used across organ types.
24 2. Perform a policy analysis of current organ distribution policies in reference to the proposed principles
25 of organ distribution.
26 3. Maintain the Ad Hoc Geography Committee through the remainder of 2018 to receive and respond to
27 community feedback and to facilitate conversations among organ-specific committee leadership
28 about policy analysis.

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